

10/021,407  
END0795USNPRemarks

## Status of Claims:

Claims 5-8 and 13-18 were rejected. Claims 5, 14, and 15 have been amended. All of the amendments are fully supported by the specification, claims, and figures as originally filed. No new matter is believed or intended to be involved.

Claims 5, 8, 13-15, and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kellogg, Jr. (U.S. Pat. No. 3,606,878) in view of Van Vaals (U.S. Pat. No. 6,430,429). Claims 6 and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kellogg, Jr. in view of Van Vaals and further in view of Gillies et al (U.S. Pat. No. 6,272,370). Claims 7 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kellogg, Jr. in view of Van Vaals and further in view of Werne (U.S. Pat. No. 5,782,764). Claims 5, 8, 13-15, and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kellogg, Jr. in view of Van Vaals and further in view of Gross (U.S. Pat. No. 3,606,878). Under MPEP 2143, in order to establish a *prima facie* case of obviousness, the prior art reference or combination of references must teach or suggest all of the limitations of a claim. A *prima facie* case of obviousness also requires that there be some teaching suggestion, or motivation to modify the references either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. MPEP 2143.01. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

Applicant notes that amended independent claim 5 recites "a hub member engaged with the distal tip, wherein the hub member is configured to cover the proximally opening hollow cavity of the distal tip to contain the capsule within the proximally opening hollow cavity of the distal tip, wherein the proximally opening hollow cavity of the distal tip is substantially closed off relative to the cutter lumen by the hub member." The combined art of record fails to teach or suggest such limitations, among others. The combined art of record therefore fails to render amended independent claim 5 obvious in accordance with MPEP 2143.03. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

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Similarly, amended independent claim 14 recites "a cap engaged with the sharpened closed distal tip, wherein the cap is configured to substantially cover the proximally opening cavity, wherein the cap is further configured to contain the material within the proximally opening cavity." The combined art of record fails to teach or suggest such limitations, among others. The combined art of record therefore fails to render amended independent claim 14 obvious in accordance with MPEP 2143.03. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

Amended independent claim 15 recites "a transverse member engaged with the sharpened distal tip, wherein the transverse member is oriented transverse to the longitudinal axis of the elongated needle, wherein the transverse member is located distally from the side port of the elongated needle and between the material and the cutter lumen, wherein the transverse member is positioned to separate the material from the cutter lumen." The combined art of record fails to teach or suggest such limitations, among others. The combined art of record therefore fails to render amended independent claim 15 obvious in accordance with MPEP 2143.03. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

Furthermore, even if the combined art of record taught or suggested all of the elements of any of the independent claims, the art is devoid of any suggestion or motivation to modify or combine the teachings of the references in order to obtain the claimed invention. Indeed, MPEP 2143.01 admonishes that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." (emphasis in original). *Actual evidence* of a suggestion, teaching, or motivation to combine prior art references must be shown. *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999). The Office has provided no evidence of a motivation as of the date of the invention to modify or combine the teachings of the prior art to obtain the invention recited in the presently amended claims. Because the requisite evidence of motivation required by MPEP 2143.01 is lacking, Applicant respectfully requests that the rejection be withdrawn.

Beyond the foregoing shortcomings with respect to the rejections of the independent claims, Applicant further notes that the dependent claims include additional limitations not taught or suggested in the art of record, thus forming independent basis for novelty and non-obviousness.

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To the extent that the present amendments constitute a narrowing of the claims, such narrowing of the claims should not be construed as an admission as to the merits of the prior rejections. Indeed, Applicant traverses the rejections and preserves all rights and arguments. While Applicant has noted several distinctions over the art of record, Applicant notes that several other distinctions exist, and Applicant preserves all rights and arguments with respect to such distinctions.

#### Conclusion

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance.

Respectfully submitted,

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JMLF

MAX F. HINDENBURG

SENIOR PATENT EXAMINER

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,407	12/12/2001	Edward A. Rhad	END-795	3685

27777 7590 06/27/2006  
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

10/021,407

RHAD ET AL.

Examiner

Art Unit

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.  
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 5-8 and 13-18 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 5-8 and 13-18 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) ☐ Notice of Informal Patent Application (PTO-152)  
 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 6/1/06 has been entered.

**DETAILED ACTION*****Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 5, 8, 13, 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals.

In regards to claims 5, 8, 13, 14, 15 and 18, Kellogg, Jr. discloses a biopsy device (Figure 1) including an elongated substantially tubular needle having a distal end (12), a proximal end, a longitudinal axis there between, a cutter lumen (Col. 2, lines 43 - 44), a non-metallic liner (20) extending along a portion of the cutter lumen; a vacuum lumen (14), a side port (10b) for receiving a tissue sample (Col. 3, lines 55 - 56); a sharpened distal tip for insertion within tissue (Col. 3, lines 45 - 49), the sharpened distal tip attached to the distal end of the needle spaced distally from the side port and a cutter (24) is movable within the cutter lumen (Col. 2, lines 62 - 64). However, Kellogg,

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Jr. fails to disclose the needle being non-metallic and the distal tip having a cavity in which an artifact creating material is disposed. Van Vaals discloses a non-metallic biopsy needle (Col. 6, lines 55 – 60) including a distal tip (6; Figure 2) having a cavity in which an artifact creating material is disposed (Figure 3; Col. 6, line 61 – Col. 7, line 34). Van Vaals discloses the artifact creating material as being selected from the group of gadolinium, titanium, aluminum, copper, brass and bronze (Col. 7, lines 1 – 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy needle as disclosed by Kellogg, Jr. to be non-metallic and to include a distal tip having a cavity in which an artifact creating material is disposed as taught by Van Vaals in order to track the needle within the body of the patient so as to guide the needle safely through the body without damaging the tissue and to guide the needle to the desired position (Col. 2, lines 41 – 50).

4. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals as applied to claims 5 and 15 above, and further in view of U.S. Patent No. 6,272,370 to Gillies et al.

In reference to claims 6 and 16, Kellogg, Jr. in view of Van Vaals discloses an MRI compatible device comprising a needle including a non-metallic material including plastic or a ceramic material (Col. 6, lines 55 – 60). Kellogg, Jr. in view of Van Vaals fail to disclose the non-metallic material comprising a thermoplastic. However, Gillies et al. discloses an MRI compatible device formed of a non-metallic material including a thermoplastic (Col. 24, lines 17 – 19). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to form the needle as



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disclosed by Kellogg, Jr. in view of Van Vaals of a thermoplastic as taught by Gilles et al. or any MRI compatible material as desired.

5. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals as applied to claims 5 and 15 above, and further in view of U.S. Patent No. 5,782,764 to Werne.

In reference to claims 7 and 17, Kellogg, Jr. in view of Van Vaals discloses an MRI compatible device comprising a needle including a non-metallic material including plastic or a ceramic material (Col. 6, lines 55 – 60). Kellogg, Jr. in view of Van Vaals fail to disclose the non-metallic material comprising a glass fiber reinforced polymer resin. However, Werne discloses an MRI compatible device including a needle comprising a glass fiber reinforced polymer resin (Col. 8, lines 36 – 65). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Lesbin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to form the needle as disclosed by Kellogg, Jr. in view of Van Vaals of a glass fiber reinforced polymer resin as taught by Werne or any MRI compatible material as desired.

6. Claims 5, 8, 13, 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals and further in view of U.S. Patent No. 5,385,563 to Gross.

In regards to claims 5, 8, 13, 14, 15 and 18, Kellogg, Jr. discloses a biopsy device (Figure 1) including an elongated substantially tubular needle having a distal end (12), a proximal end, a longitudinal axis there between, a cutter lumen (Col. 2, lines 43 - 44), a non-metallic liner (20) extending along a portion of the cutter lumen; a vacuum lumen (14), a side port (10b) for receiving a tissue sample (Col. 3, lines 55 – 56); a sharpened distal tip for insertion within tissue (Col. 3, lines 45

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- 49), the sharpened distal tip spaced distally from the side port attached to the distal end of the needle and a cutter (24) is movable within the cutter lumen (Col. 2, lines 62 - 64). However, Kellogg, Jr. fails to disclose the needle being non-metallic and the distal tip having a cavity in which an artifact creating material is disposed. Van Vaals discloses a non-metallic biopsy needle (Col. 6, lines 55 - 60) including a distal tip (6; Figure 2) having a cavity in which an artifact creating material is disposed (Figure 3; Col. 6, line 61 - Col. 7, line 34). Van Vaals discloses the artifact creating material as being selected from the group of gadolinium, titanium, aluminum, copper, brass and bronze (Col. 7, lines 1 - 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy needle as disclosed by Kellogg, Jr. to be non-metallic and to include a distal tip having a cavity in which an artifact creating material is disposed as taught by Van Vaals in order to track the needle within the body of the patient so as to guide the needle safely through the body without damaging the tissue and to guide the needle to the desired position (Col. 2, lines 41 - 50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to ensure that the artifact creating material is spaced distal of the side port as taught by Gross in order to allow a user to determine proper placement of the device during use (See Abstract).

7. Claims 5, 8, 13, 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals.

In regards to claims 5, 8, 13, 14, 15 and 18, Kellogg, Jr. discloses a biopsy device (Figure 1) including an elongated substantially tubular needle having a distal end (12), a proximal end, a longitudinal axis there between, a cutter lumen (Col. 2, lines 43 - 44), a non-metallic liner (20) extending along a portion of the cutter lumen; a vacuum lumen (14), a side port (10b) for receiving a tissue sample (Col. 3, lines 55 - 56); a sharpened distal tip for insertion within tissue (Col. 3, lines 45

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- 49), the sharpened distal tip attached to the distal end of the needle and a cutter (24) movable within the cutter lumen (Col. 2, lines 62 – 64). However, Kellogg, Jr. fails to disclose the needle being non-metallic and the distal tip having a cavity in which an artifact creating material is disposed. Van Vaals discloses a non-metallic biopsy needle (Col. 6, lines 55 – 60) including a distal region having a cavity in which an artifact creating material is disposed (Figure 3; Col. 6, line 61 – Col. 7, line 34). Van Vaals discloses the artifact creating material as being selected from the group of gadolinium, titanium, aluminium, copper, brass and bronze (Col. 7, lines 1 – 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy needle as disclosed by Kellogg, Jr. to be non-metallic and to include a distal region having a cavity in which an artifact creating material is disposed as taught by Van Vaals in order to track the needle within the body of the patient so as to guide the needle safely through the body without damaging the tissue and to guide the needle to the desired position (Col. 2, lines 41 – 50). It would have been obvious to one having ordinary skill in the art to place artifact creating material in a cavity in the distal tip which is spaced distally of the side port as taught by Chin et al. because accurate knowledge of the location of the extreme distal end of the biopsy device is necessary to avoid injury of internal organs (Col. 6, lines 48 – 57).

#### *Response to Arguments*

8. Applicant's arguments filed 10/13/05 have been fully considered but they are not persuasive. Applicant asserts that rejection of claims 5, 8, 13 – 15 and 18 under 35 U.S.C. §103(a) as being as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals is improper because the limitation "wherein said material is spaced distally from said side port of said needle" is not taught or suggested by the proposed combination. Additionally Applicant asserts that the combination of Kellogg, Jr. in view of Van Vaals is improper

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because there is no suggestion or motivation to combine the teachings of the references in order to obtain the claimed invention. However the Examiner disagrees. Kellogg, Jr. teaches a standard biopsy needle having a distal tip that is spaced distally of the side port (Figure 4). Van Vaals teaches an improved biopsy needle (Col. 6, lines 55 - 57) being formed of a non-metallic material and having a cavity in the distal tip in which an artifact inducing material is placed (Col. 6, line 48 - 64). Van Vaals teaches that such a biopsy needle is beneficial because it allows introduction of the needle into a patient while being guided by magnetic resonance imaging. The Examiner has used such a teaching as the motivation to modify the needle as disclosed by Kellogg, Jr. with the teachings of Van Vaals. The Examiner maintains that the motivation to modify the prior art to arrive at the present invention has come from the references themselves and renders the claims unpatentable under 35 U.S.C. 103(a) over Kellogg, Jr. in view of Van Vaals. By modifying the distal tip of Kellogg, Jr. that is placed distally of the side port with a distal tip containing an artifact creating material in a recess as taught by Van Vaals, the limitation "wherein said material is spaced distally from said side port" is rendered obvious.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.